FEB 0 8 2002

SECTION 18: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

18.1 SUBMITTER INFORMATION

a. Company Name:	Nidek, Inc.
b. Company Address:	47651 Westinghouse Drive Fremont, CA 94539
c. Company Phone: Company Facsimile:	(510) 226-5700 (510) 226-5750
d. Contact Person:	Hiro Matsuzaki Quality Assurance Manager
e. Date Summary Prepared:	January 4, 2002

18.2. DEVICE IDENTIFICATION

a. Trade/Proprietary Name:	Epi-Star Surgical Laser System, Models A and B
b. Classification Name:	Surgical Laser Instrument 21 CFR 878.4810 78 GEX

18.3 IDENTIFICATION OF PREDICATE DEVICES

Company	Device	510(k) No.	Date Cleared
Nidek, Inc.	Epi-Star Surgical Laser System	K990119	07/27/2000

18.4 DEVICE DESCRIPTION

The Epi-Star Surgical Laser System is an 800 nm continuous wave device coupled with cooling accessory. The Epi-Star laser is self-limiting in the size of

spots (2, 3, 4, and 5mm), output power, dwell time, density and fluence rates. The Epi-Star Surgical Laser can achieve fluence rates of up to 400 J/cm^2 when coupled with the cooling accessories. The treatment parameters for the classifications of various skin types is provided. The Epi-Star laser can be coupled with either a scanner handpiece that has a cooling window (Model A) or with a scanner and cold air system (Model B).

18.5 SUBSTANTIAL EQUIVALENCE

The Epi-Star Surgical Laser System with the proposed modifications is substantially equivalent to the current Epi-Star Surgical Laser System that is currently in commercial distribution by Nidek, Inc.

The fundamental technical characteristics of the Epi-Star Surgical Laser System are the same as those of the predicate device and the indications for use has not changed with the modifications of the device.

18.6 INDICATIONS FOR USE

The Epi-Star Surgical Laser System is intended to be used for Plastic Surgery and Dermatology, with the intended uses for the treatment of vascular and pigmented lesions and for the removal of hair in skin types I – VI.

18.7 TECHNOLOGICAL CHARACTERISTICS

The modifications to the Epi-Star Laser System allow for higher fluence rates of up to 400 J/cm^2 for the treatment of vascular and pigmented lesions and the removal of hair. The increased fluence rates are dependent on the skin types to be treated and are self-limiting by the laser system. The output power of the system is from 5 - 60 Watts, the aiming beam is 620 – 650 nm and the pulse duration is 5 – 700 ms. Spot sizes of 2, 3, 4, and 5mm can be accomplished with the Epi-Star. Model A includes a scanner with a 2-TE chip cooling window and Model B includes a scanner attached to a cold air system. The current Epi-Star Laser

System allows for fluence rates of up to 50 J/cm^2. The current Epi-Star includes a scanner with a 1-TE chip cooling window.

18.8 PERFORMANCE DATA

Performance testing was conducted on the Epi-Star Surgical Laser System. System and component testing was completed based on product specifications and hazard effects determined from the risk analysis. A preclinical animal study was conducted to determine the safety of the Epi-Star Surgical Laser System with the higher fluence rates. The Epi-Star Surgical Laser System was found to perform as intended.

18.9 CONCLUSION

This notification contains all information required by 21 CFR 807.87. The Epi-Star Surgical Laser System with the higher fluence rates was found to perform as intended during validation testing and in preclinical animal studies. The Epi-Star Surgical Laser System is substantially equivalent to the current Epi-Star Surgical Laser System in commercial distribution. The Epi-Star Surgical Laser System is intended for the treatment of vascular and pigmented lesions and for the removal of hair.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 8 2002

Nidek, Inc.
c/o Ms. Carol White
Patterson Consulting Group, Inc.
21521 Hummingbird Street
Trabuco Canyon, California 92679

Re: K013864
Trade/Device Name: Epi-Star Surgical Laser System, Models A and B and Zimmer Elektromedizin Cryo 5
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 19, 2001
Received: November 21, 2001

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K013864

Device Name: Epi-Star Surgical Laser System, Models A and B

Indications for Use: The Epi-Star Surgical Laser System is intended to be used for Plastic Surgery and Dermatology, with the intended uses for the treatment of vascular and pigmented lesions and for the removal of hair in skin types I – VI.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013864

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)